Safety Notification Update

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, PM2160, PM2172, PM2240, PM2260, PM2272

October 2021

Dear Physician or Healthcare Professional:

Abbott is following up on our March 2021 customer Safety Notification communication affecting a subset of Assurity™ and Endurity™ pacemakers which may be impacted by intermittent incomplete mixing of epoxy in the manufacturing process. This issue may potentially allow moisture ingress into the pulse generator header, introducing a risk of interrupting device functionality. As described in the March 2021 communication (see hyperlink below), this specific manufacturing process is no longer in use, and no affected devices remain available for implant.

There have been no reports of serious harm to patients resulting from this issue.

In March 2021, Abbott notified physicians that approximately 95,000 devices manufactured on specific manufacturing equipment were potentially susceptible to this issue. Reported clinical impact has included loss of telemetry / communication, reduced battery longevity, loss of pacing, and/or shortened duration between Elective Replacement Indicator (ERI) and End of Service (EOS).

Since March of 2021, Abbott's post-market surveillance process has identified 29 devices exhibiting moisture ingress that were out of the range of the March 2021 communication. Based on further investigation of the reported events, Abbott is expanding the communication to include approximately 240,000 additional devices. This expanded population has demonstrated an observed issue rate of 0.01%.

Abbott records indicate you are following one or more patients implanted with a potentially affected device as noted in the enclosed Patient List. The overall risk profile is low, though please reference the patient management recommendations below.

Abbott has deployed a new **Electronics Performance Indicator (EPI) tool to assist in patient management** in patients followed with Merlin.net**.** The EPI tool supplements ERI using data available on Merlin.net to identify abnormal electrical system behavior resulting from loss of hermeticity. The EPI tool estimated sensitivity is 87% (ability to detect abnormal electrical system behavior of this nature) and estimated specificity is > 99.9%. The EPI tool has been designed to provide earlier indication, with detection occurring on average 6 weeks before an interruption of a device function (e.g. loss of telemetry / communication, etc.). The EPI tool is an Abbott surveillance process that reviews data from all devices within the affected population communicating with Merlin.net. If an EPI signal is detected, Abbott will notify the clinic using the email contact information in Merlin.net. Please ensure your clinic contact information in Merlin.net is current.

Patient Management Recommendations:

Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following updated guidelines:

- **Prophylactic generator replacement is not recommended.** This is due to the very low rate of occurrence, and the low potential for patient harm when replacement is performed following an EPI notification or an ERI/EOS alert.
- **Routine follow-up should remain as per standard of care and clinical protocol.** Review device function including measured battery voltage or any unexpected change in battery consumption. Also, evaluate the potential for risk in patients who are pacemaker dependent and are unable to be reliably followed using remote monitoring.

- **Prompt replacement for devices that receive an EPI notification, reach ERI/EOS,** or experience one of the clinical impacts listed above, commensurate with the patient's underlying clinical condition.
- **When possible, monitor patients using Merlin.net** to benefit from alert monitoring between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI and EOS alerts and will now also include monitoring of the safety notification population by the EPI tool.

Please return a completed Acknowledgement Form and maintain a record of this notice along with a copy of the completed Acknowledgement Form to ensure effectiveness of the communication.

As an additional resource, a device lookup tool has been made available at www.cardiovascular.abbott/pacemaker-lookup and can aid you or your practice in confirming impact for those patients you are following.

Additionally, the initial March 2021 communication is located at:
https://www.cardiovascular.abbott/content/dam/bss/divisionalsites/cv/pdf/reports/assurity-endurity-032021-DDL-US.pdf.

Abbott will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization, as appropriate.

Adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Should you have any questions about this notice, please contact Abbott Technical Support at 1-800-722-3774 (U.S.). Please work with your Abbott Representative to return any explanted devices to Abbott for product evaluation and analysis.

We sincerely apologize for any difficulties or inconvenience that this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

Robert Blunt

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management